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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,559	02/08/2002	Eric F. Bernstein	BERN-0050	2377

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EXAMINER

PARAS JR, PETER

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 05/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

9/22

Office Action Summary

Application No.

09/913,559

Applicant(s)

BERNSTEIN, ERIC F.

Examiner

Peter Paras, Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2004.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-6 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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Applicant's amendment received on 3/5/04 has been entered. Claims 1-6 have been amended. Claims 1-6 are pending and are under current consideration.

Specification

The abstract received on 3/5/04 has been entered.

Claim Objections

Claim 1 is objected to because of the following informalities: the phrase "solar stimulating" is incomplete and should be "solar stimulating radiation". Appropriate correction is required.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The previous rejection is maintained for the reasons of record advanced on pages 2-5 of the Office action mailed on 11/5/03.

Applicant's arguments filed 3/5/04 have been fully considered but they are not persuasive. Applicants argue the specification has provided ample guidance for creation of transgenic mice whose genomes comprise a truncated human elastin promoter, which is operably linked to a reporter gene. Applicants have pointed to pages 3, 5, 7 and example 1 of the specification for support.

In response, the Examiner maintains the instant specification has failed to provide sufficient guidance to enable the instant invention to the extent of truncated human elastin promoters. First, the claims do not require expression of the reporter gene. Reporter expression can be considered a phenotype and should be recited in the claims. Otherwise it appears the claimed mice have no phenotype. In light of such it is maintained that the phenotype resulting from transgene expression is unpredictable. See pages 3-5 of the Office action mailed on 11/5/03 as well as Wall and Houdebine on page 4 of the Office action mailed on 11/5/03. Second, the breadth of the claims embraces all possible truncated forms of the human elastin promoter. For example, while the specification has taught that the full-length human elastin promoter is 5.2KB, the claims embrace truncated forms of the promoter that can range from 10 bp to 100 bp to 5.1 KB in length. The specification has not provided guidance correlating to activity of the various truncated promoter forms embraced by the claims. It is unpredictable if all truncated human elastin promoters are capable of directing expression of a reporter gene. See Kahari et al (Journal of Biological Chemistry, 1990, 265(16): 9485-9490), which provides a deletion analysis of putative promoter regions 5' to the human elastin gene. In particular, on page 9487, in Figure 3, Kahari provides

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evidence that certain truncated forms of the human elastin promoter contained within plasmids EP50 and EP60 have 0% activity. Therefore it is unpredictable if all truncated human elastin promoters are capable of directing reporter gene expression. Finally, in referring to possible truncated forms of the human elastin promoter, the specification on page 5, for example actually refers to plasmids and not the actual promoter sequences. In any event such reference amounts to an improper incorporation by reference.

Applicants are reminded the MPEP 608.01(p) states that essential material may not be incorporated by reference to non-patent publications. Truncated forms of the human elastin promoter appear to be essential material as they are required by the claims. Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. *In re de Seversky*, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). See MPEP § 201.06(c) and MPEP § 608.01(p).

Particular attention should be directed to specific portions of the referenced document where the subject matter being incorporated may be found. In light of such it appears the instant specification has failed to provide guidance necessary for making and using truncated forms of human elastin promoter capable of directing expression of a reporter gene. The specification has failed to provide guidance or relevant teachings correlating to the regions of the human elastin promoter necessary for activity that would enable the skilled artisan to produce and use truncated forms of the human elastin promoter.

Accordingly, the rejection is maintained for the reasons of record.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The previous rejection is maintained for the reasons of record advanced on pages 6-7 of the Office action mailed on 11/5/03.

Applicant's arguments filed 3/5/04 have been fully considered but they are not persuasive. Applicants assert that multiple truncated human elastin promoters have been described by the instant specification and point to page 5 for support. Applicants further assert that a truncated human elastin promoter provides a 20 to 30-fold increase in activity. Applicants argue that evidence of a known structural relationship between truncated and full-length human elastin promoters has been presented. Finally, Applicants submit the instant claims have been amended to clarify that truncated elastin promoter is activated by UV or solar simulating radiation.

In response, the Examiner maintains that the truncated forms of the human elastin promoter embraced by the claims have not been described by the instant specification. It is further maintained the evidence of record has not provided evidence of a known structural relationship of any truncated human elastin promoter and the full-length elastin promoter. The instant evidence of record has not described which elements or domains within the structure of the human elastin promoter are necessary for function and has failed to provide a structural relationship between the full-length and truncated promoters. No evidence has been provided as to which truncated

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promoters are UV responsive. Applicants have pointed to page 5 of the specification as evidence of disclosure of truncated elastin promoters. However, the disclosure on page references plasmids comprising various parts of the human elastin promoter and not the actual promoter sequences themselves. Thus, it is not known which regions of the human elastin promoter are contained within the plasmids as no correlation was made to a sequence and no sequences have been provided (so it is not understood which sequence provided the 20-30-fold increase in activity). In any event, attempts to incorporate truncated forms of the human elastin promoter by reference were improper. Applicants are reminded the MPEP 608.01(p) states that essential material may not be incorporated by reference to non-patent publications. Truncated forms of the human elastin promoter appear to be essential material as they are required by the claims. Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. In re de Seversky, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). See MPEP § 201.06(c) and MPEP § 608.01(p). Particular attention should be directed to specific portions of the referenced document where the subject matter being incorporated may be found.

Accordingly, the previous rejection is maintained for the reasons of record.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 3-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3-4 recite the limitation "the determined human elastin promoter activity" in lines 9-10. There is insufficient antecedent basis for this limitation in the claim.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is (571) 272-0732. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 571-272-0804. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Official Fax Center number is (703) 872-9306.

Inquiries of a general nature or relating to the status of the application should be directed to Dianiece Jacobs whose telephone number is (571) 272-0532.

Peter Paras, Jr.

PETER PARAS, JR.
PRIMARY EXAMINER

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